OCT 2 5 2000

K002675

510 (k) - Summary as Required by 807.92 (c)

August 15, 2000

FDA Contact at PDI, Inc.:	Rodolfo A. Carballo 4500 E. Speedway Blvd. # 50 Tucson, AZ 85712 Tel: (520) 881-2556 Fax (520) 881-2862
Classification Name:	76 EJT – Alloy Gold Based for Clinical Use
Classification Number:	§ 872.3060 Gold-based alloys and precious metal alloys for clinical use.
Common / Usual Name:	Accelerated Electroforming Gold Solution.
Proprietary Name:	**Millennium Edition 2000 Accelerated Electroforming System.**
Intended Use:	Fabrication of pure 24 karat 99,96% gold substructure for porcelain fused to metal dental restorations.
Description:	The **Millennium Edition 2000 – Gold Electroforming System** consist of an accelerated cyanide free gold electroforming solution and a DC/Digital power control unit, to fabricate pure 24 karat 99.96% gold substrates (copings) for porcelain fused to metal crown restorations. The Millennium Edition 2000 electroforming gold solution composition and ingredients consist mostly of Sodium Sulfite and Sodium Gold Sulfite conformed to a specific volume concentration, grams of gold per liter of solution.
Substantial Equivalence:	The biocompatibility of pure gold has been well documented. Pure gold has been historically used with great deal of success in the dental field for various types of restorations. The **Millennium Edition 2000 – Gold Electroforming System** and other similar products on the market enhance the application of clinically released porcelain to be fused to

gold copings safely and with a great deal of esthetics. In addition to excellent biocompatibility, the warmth and vitality of a pure gold restoration is by far, sure to please both, dentist and patient. The **Millennium Edition 2000 – Gold Electroforming System** is a direct extension of the ProGold Electrocoping System, with the electronics made also by PDI, Inc. and distributed by MicroSelect, a Div. of MicroDental, Dublin, CA. 510(k) K-980613.

Additional substantially equivalence to: The Midas Gold Electroforming System, distributed in the USA by Autenal Inc. 4101 W. 51st Street, Chicago, IL 60632. 510(k) K-955509. Also substantially equivalent to: The GRAMMAT Gold electroforming system, distributed in the USA by Gramm Technology Inc. 3016 PS Business Center, Woodbridge, VA 22192. 510(k) K-911042.

Performance Standards: None established under section 514.

Labeling: Labels will include batch (lot) numbers to comply with FDA GMP requirements.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 25 2000

Mr. Rodolfo A. Carballo
President
Products Development Industries, Incorporated
4500 East Speedway Boulevard
Tucson, Arizona 85712

Re: K002675
Trade Name: Millennium Edition 2000 Accelerated Electroforming System
Regulatory Class: II
Product Code: EJT
Dated: August 25, 2000
Received: August 28, 2000

Dear Mr. Carballo:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note:

this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) number: ~~Not Known~~ K002675

Device Name: **Millennium Edition 2000 – Gold Electroforming System**

Indications For Use: Fabrication of 24 Karat 99.96% pure Gold substrate (Coping) for porcelain fused crown/bridges restoration for dentistry applications.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

Sandra L. Shing for MSR
(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K002675